

REMARKS/ARGUMENTS

In response to the official action of November 24, 2003, applicant requests continued examination in light of the foregoing amendments. Claim 1 has been amended to specify that the medical device is a Foley catheter, that is, a urinary drainage catheter having an inflatable anchoring balloon at its distal end. Accordingly, claims 6-8, 29 and 44 have been cancelled. Claim 1 also has been amended to define the "fluid acceptor" as an anchoring balloon and to clarify that the elastomeric reservoir bulb is a reservoir for fluid by which the balloon may be inflated.

Applicant's Invention

Applicant's invention is directed to a Foley catheter for urine drainage from a patient's bladder. The catheter includes a self-contained liquid reservoir at its proximal end connected by a lumen within the catheter shaft to an anchor balloon at the distal end of the catheter. When liquid is permitted to flow from the reservoir, it inflates the balloon to anchor the catheter in the bladder. A second lumen in the catheter shaft drains urine from the bladder to the proximal end of the catheter.

A control device situated within the lumen controls the flow of liquid from the reservoir to the anchor balloon. The control device comprises a plug having a coaxial stem (27) attached to an annular part (26) having a diameter at least twice that of the stem. The stem seals the lumen defined by the annular part. The stem and the annular part meet at a weakened parting line along which the plug can be fractured by manipulation of the exterior of the catheter shaft. The separation of the plug along the parting line opens up fluid communication through the plug along the catheter lumen from the reservoir to the anchor balloon.

The invention improves over the prior art, in which U-shaped clips were applied to the external surface of the catheters to pinch the lumen closed. Such clips may damage the catheter.

The Cited Prior Art

U.S. Patent 4,018,231 (Wallace)

The Wallace patent is directed to a tracheal tube for introducing or removing gas through the trachea. The tube includes an inflatable cuff (18) at its distal end which is inserted into a patient in a non-inflated condition and then inflated in order to seal and secure the position of the cuff against the internal wall of the trachea. The cuff is inflatable through an inflation lumen (15) that includes, at its proximal end, a check valve within a housing (24) having a passageway (26) and a housing inlet (28), all of which are situated within a pilot balloon (46), and provide a passage through which gas may flow through the pilot balloon and into or out of the inflatable cuff. The distal cuff is inflatable by a syringe connectable to the housing inlet 28. Insertion of the syringe deforms the housing such that a movable plug 34 of the check valve is freed to permit gas to flow through the check valve to inflate the distal cuff. When the syringe is removed, the housing returns to its relaxed shape in which the plug seals the lumen. The pilot balloon, which is outside of the patient, inflates and deflates in unison with the distal balloon and serves to provide a visual indication of the state of inflation of the distal cuff, i.e., an inflated pilot balloon indicates an inflated cuff and a deflated pilot balloon indicates a deflated cuff.

U.S. Patent 4,116,201 (Shah)

The Shah patent discloses an endotracheal tube having and includes a balloon (20) at its distal end connected through a lumen (24) to an inflation control device (30) for inflating and deflating the balloon. The inflation control device (30) includes a housing (38) that contains a normally closed valve element (70). The valve element is moveable between its normally closed configuration and an open configuration in response to insertion of a syringe into the housing. Movement of the valve element (70) separating shoulders (74) from seat (50) allows fluid to flow therethrough. (see col. 4, line 53-col. 5, line 20 of Shah). A tapered plug (98) is also sized to selectively seal the inflation port (48); removal of the plug allows the insertion of a syringe.

U.S. Patent 3,602,226 (Ericson)

The Ericson patent discloses what appears to be a Foley-type catheter having a distal inflatable balloon and a proximal reservoir retaining a fluid under pressure in readiness to inflate the distal balloon through an inflation lumen. A clamp 15 is used to pinch the inflation lumen closed. When the clamp is removed, the fluid under pressure in the reservoir is forced through the inflation lumen to inflate the distal balloon.

Rejections Under 35 U.S.C. §102

Anticipation under 35 U.S.C. §102 requires each and every limitation of the claim to be disclosed in a single prior art reference, either expressly or inherently. The anticipating reference must disclose the elements in the arrangement called for by the claim. If any limitation of the claim is missing, the reference does not anticipate.

Reconsideration is requested of the rejection of claims 1-8, 16-24 and 26-29 as anticipated by U.S. patent 4,018,231 to Wallace. Claim 1 includes the limitation that the device is a Foley catheter having a fluid-storing reservoir at its proximal end and an inflatable cuff at its distal end. While Wallace may disclose a syringe-actuable check valve by which fluid may be pumped from the syringe through the inflation lumen to the distal cuff, the check valve does not include a plug that can be parted into two separate parts, nor does it disclose a plug with a parting line to facilitate the separation by manipulation from outside the lumen. Moreover, Wallace does not disclose a plug having an annular part which necessarily defines a passage through the plug, nor does it disclose a plug having a stem in which the diameter of the annular part is at least twice that of the stem, as claimed. Wallace also fails to disclose a reservoir bulb as claimed by applicant in which fluid stored in the reservoir bulb may be transferred through the inflation lumen to the balloon at the distal end of the catheter. With applicant's device the fluid in the reservoir serves to inflate the distal balloon. In other words, the reservoir bulb deflates as the distal balloon inflates. Wallace, on the other hand, discloses a proximal pilot balloon, which inflates and deflates in phase with the distal balloon, the pilot balloon serving merely to provide a visual indication of the state

of inflation (or deflation) of the distal balloon. The pilot balloon does not itself serve as a reservoir and cannot reasonably be considered as applicant's claimed "reservoir bulb".

Each of claims 2-8, 16-24 and 26-29 depends directly or indirectly from claim 1 and is not anticipated by Wallace for the same reasons.

Reconsideration is requested of the rejection of claims 1-8, 16-24 and 26-29 as anticipated by U.S. patent 4,116,201 to Shah. Shah, as Wallace, appears to be directed to an endotracheal tube having an inflatable cuff at its distal end to effect a seal against the inner surface of the patient's trachea. The cuff is inflatable and deflatable by a syringe that is coupled to a check valve that is movable between open and closed positions in response to insertion of the syringe. Shah fails to disclose the limitations of claim 1 discussed above in connection with Wallace. In particular, Shah does not disclose an elastomeric reservoir bulb at the end of the device for storing inflation fluid under pressure. Shah does not disclose a plug having the limitations defined in claim 1 and described above in connection with Wallace.

Each of claims 2-8, 16-24 and 26-29 depends directly or indirectly from claim 1 and includes the same limitations. None of those claims is anticipated by Shah for the same reasons.

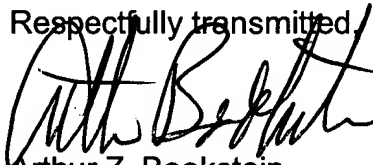
Obviousness Rejections (35 U.S.C. §103)

Reconsideration is requested of the rejection of claims 1-8, 16-24, 26-29 and 35-38 as unpatentable over the combined disclosures of Wallace and Ericson patent 3,602,226. Ericson fails to disclose those features of applicant's invention, as defined in claim 1 and discussed above, that are missing from Wallace. Indeed, Ericson is directed to the type of prior art Foley catheter over which applicant's invention is considered to be an improvement. Ericson discloses a simple clamp to prevent flow of inflation liquid from the reservoir through the inflation lumens of the distal cuff. See the discussion of that prior art in applicant's specification in the last paragraph, page 1, continued on page 2. Where neither Ericson nor Wallace discloses the above discussed limitations of claim 1, there is no basis for the notion that their combination would have suggested that invention. To the extent that the Ericson patent appears to

Ser. No. 09/720,309
Amdt. dated May 24, 2004
Reply to Office action of November 24, 2003

have been cited for its disclosure of "... a jacket or sleeve 18 which is shrunk into contact to the reservoir 17" (2:26-28) that is irrelevant to the subject matter defined by claim 1. Additionally, there is no suggestion of a motivation for such combination or of how a "shrunk sleeve" might be combined with any disclosure of Wallace. The failure of Ericson to disclose those features of claim 1 that are missing from Wallace requires withdrawal of the rejection. Where each of claims 2-8, 16-24 and 26-29 depends from, directly or indirectly, and includes all the limitations of claim 1, those claims are not suggested by the disclosures of Wallace and Ericson. Those rejections are improper as well.

Respectfully transmitted,



Arthur Z. Bookstein
Registration No. 22,958
KIRKPATRICK & LOCKHART LLP
75 State Street
Boston, Massachusetts 02109-1808
Customer No.: 022832
Tel: 617-261-3100
Attorneys for Applicants

Attorney Docket No.: A0008/7004
Date: May 24, 2004